

IT IS CLAIMED:

1. A method of providing anti-infective activity to a medical device, comprising

- a) providing a medical device which is at least in part within a patient;
- b) exposing the medical device to an anti-infective oxidant; and
- 5 c) transferring the anti-infective oxidant into a wall of the medical device.

2. The method of claim 1 wherein the medical device has a lumen, and including exposing a wall defining the lumen to the anti-infective oxidant.

10 3. The method of claim 2 wherein the medical device is a catheter having a shaft defining the lumen and having a balloon with an interior in fluid communication with the lumen of the catheter shaft, and including exposing an inner surface of the balloon to the anti-infective oxidant.

15 4. The method of claim 2 including delivering a formulation which generates the oxidant into the lumen of the medical device.

20 5. The method of claim 4 including inserting a tubular delivery member into the lumen of the medical device, the tubular delivery member having a lumen configured to deliver the oxidant generating formulation into the lumen of the medical device.

6. The method of claim 4 including, after step (c), removing the oxidant generating formulation from the lumen of the medical device.

7. The method of claim 4 including inhibiting expulsion of the oxidant generating formulation from the lumen of the medical device by providing a viscosity increasing hydrogel in the oxidant generating formulation.

5

8. The method of claim 4 wherein the anti-infective oxidant comprises elemental iodine, and including combining a first solution comprising an iodide and a second solution comprising an iodate such that an elemental iodine generating formulation is produced, and delivering the elemental iodine generating formulation to the lumen of the medical device.

9. The method of claim 4 wherein the anti-infective oxidant comprises elemental iodine and the oxidant generating formulation comprises an iodide and an oxidoreductase, and including exposing the oxidoreductase to a substrate to generate protons or an iodide oxidizing agent, so that the oxidant generating formulation produces elemental iodine.

10. The method of claim 9 including exposing the medical device to a body fluid having the substrate to generate protons or an iodide oxidizing agent, so that the oxidant generating formulation produces elemental iodine when contacted with the body fluid.

11. The method of claim 4 wherein the anti-infective oxidant comprises elemental iodine and the oxidant generating formulation comprises an iodate, and including exposing the iodate to a reducing agent to generate elemental iodine.

12. The method of claim 2 including inserting an oxidant releasing member into the lumen of the medical device.

---

13. The method of claim 12 wherein the oxidant releasing member has an elongated body  
5 configured to be slidably inserted into the lumen of the medical device, and further including,  
before step (b), exposing the oxidant releasing member to a formulation which generates the  
oxidant so that the oxidant diffuses into the oxidant releasing member.

14. The method of claim 13 wherein the anti-infective oxidant comprises elemental iodine,  
10 and including exposing the oxidant releasing member to an elemental iodine generating  
formulation comprising an iodide, and iodate and a proton source.

15 The method of claim 14 including transferring about 2 ppm to about 300 ppm of the  
oxidant from an exterior surface of the medical device to the patient.

16. The method of claim 1 including, after step (c), diffusing the oxidant to an outer surface  
of the medical device.

17. The method of claim 1 wherein the anti-infective oxidant comprises elemental iodine, and  
20 including transferring about 2 ppm to about 300 ppm of the elemental iodine from an exterior  
surface of the medical device to the patient.

18. The method of claim 1 including transferring the anti-infective oxidant within about 1 to about 30 minutes.

---

19. The method of claim 1 wherein the anti-infective oxidant is elemental iodine, and including preventing the binding of the elemental iodine within the wall of the medical device.

20. The method of claim 19 wherein the binding of the element iodine is prevented by providing a medical device which is free of iodine binding agents.

21. The method of claim 4 wherein the formulation includes a binding agent which is bindable to the anti-infective oxidant, and including binding an amount of the generated anti-infective oxidant to the binding agent to thereby inhibit transfer of the bound anti-infective oxidant into the medical device wall.

22. The method of claim 21 wherein the binding agent is selected from the group consisting of silicone oil, mineral oil, cadexomers, and polyvinylpyrrolidone, and including increasing a duration over which at least about 2 ppm of the anti-infective oxidant is transferred into the medical device wall.

23. The method of claim 21 wherein the anti-infective oxidant comprises elemental iodine, the binding agent comprises polyvinylpyrrolidone, and the polyvinylpyrrolidone is about 1% to about 10% weight per unit volume of the formulation, and including increasing a duration over

which at least about 2 ppm of the elemental iodine is transferred from an exterior surface of the medical device to the patient.

---

24. The method of claim 4 including positioning an insert member into the lumen of the medical device to thereby reduce the amount of formulation delivered into the medical device lumen.

25. An anti-infective oxidant releasing member, comprising an elongated body configured to be slidably disposed within a lumen of a medical device and an anti-infective oxidant releasably contained within the elongated body.

26. The anti-infective oxidant releasing member of claim 25 wherein the elongated body comprises a solid rod.

27. The anti-infective oxidant releasing member of claim 26 wherein the solid rod further includes at least one channel on an outer surface of the rod configured to allow fluid flow therein.

28. The anti-infective oxidant releasing member of claim 25 wherein an outer diameter of the elongated body is about 90% to about 5% less than an inner diameter of the lumen of the medical device.

29. The anti-infective oxidant releasing member of claim 25 wherein an outer diameter of the elongated body is about 20% less than an inner diameter of the lumen of the medical device.

30. The anti-infective oxidant releasing member of claim 25 wherein the oxidant comprises elemental iodine.

5 31. The anti-infective oxidant releasing member of claim 26 wherein the elongated body is formed of a polymeric material, and wherein elemental iodine is diffusible within the polymeric elongated body.

32. A method of providing anti-infective activity to a medical device, comprising

10 a) exposing the medical device a solution which produces an anti-infective oxidant;  
and

b) transferring a sufficient amount of anti-infective oxidant into a wall of the medical device to provide the medical device with anti-infective activity.

15 33. The method of claim 32 wherein the solution is aqueous and the anti-infective oxidant is elemental iodine.

34. The method of claim 33 wherein the aqueous solution produces at least about 0.1 ppm of elemental iodine.

20 35. The method of claim 33 including transferring about 2 ppm to about 300 ppm of the elemental iodine from an exterior surface of the medical device to the patient.

36. The method of claim 35 wherein step (a) further comprises exposing the medical device a single time to the aqueous solution.

37. The method of claim 36 wherein the aqueous solution produces about 2 ppm to about 10 ppm of iodine.

38. The method of claim 33 including transferring not greater than about 1000 micrograms a day of the elemental iodine from an exterior surface of the medical device to the patient.

39. A method of providing anti-infective activity to a medical device, comprising

a) exposing an oxidant releasing member to a formulation which generates an anti-infective oxidant, so that the anti-infective oxidant diffuses into the oxidant releasing member; and

b) exposing the medical device to the oxidant releasing member so that the anti-infective oxidant diffuses from the oxidant releasing member into a wall of the medical device.